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KERATRON® SCOUT

Videokeratoscope

INSTALLATION AND OPERATING MANUAL

OPTIKON 2000 S.p.A.

Via del Casale di Settebagni, 13 - 00138 Rome Italy
Phone +39 06 8888355 - Fax. +39 06 8888440
e-mail mailto:sales@optikon.com - www.optikon.com

Optikon 2000 SpA is an ISO 9001 and ISO 13485 certified company which manufactures surgical and diagnostic devices for ophthalmology.

Its products are manufactured to satisfy the requirements of 93/42/EEC Medical Devices Directive.

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1 DISCLAIMER

OPTIKON 2000 S.p.A. requires the user of this system to carefully read specific warnings found in this manual. It is responsibility of the user to provide its personnel with a thorough understanding of the equipment operation before use. In no event shall Optikon 2000 S.p.A. be liable for any injury, incidental or consequential damages incurred by the purchaser, users or patients as a result of operation of the product.

Use of this system is a matter of professional medical judgment in all cases. Optikon 2000 S.p.A. is not responsible for any clinical problem resulting from mishandling this equipment and makes no medical recommendations.

Optikon 2000 S.p.A. declares to be liable for safety, reliability and performance only if:

- upgrades, calibrations, repairs are carried out by OPTIKON 2000 S.P.A. authorized personnel
- the system is used in accordance with its instructions for use
- the mains electric installation to which the system is connected complies with the IEC or UL Safety Regulations

IMPORTANT NOTICE

Every effort has been made to have all the illustrations and information accurately represent the product and its operation as it actually was at the time this operation manual was printed. Changes in some items may be made during the life of this manual, so that we may effectively continue to meet the requirements of users. On occasion, these changes may be made without notice.

OPTIKON 2000 S.p.A.

Via del Casale di Settebagni, 13
00138 Rome Italy

Phone +39 06 8888355
Fax +39 06 8888440
e-mail sales@optikon.com
www.optikon.com

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2 LIMITED WARRANTY CONDITIONS

All OPTIKON 2000 S.P.A. equipment and accessories sold and installed in the European Union are guaranteed against defective workmanship and faulty parts for ONE YEAR, from the date of the invoice. Warranty on consumable materials is limited to the first use.

Please, inquire with your local Optikon Distributor for warranty conditions in countries outside the European Union.

All items under warranty will be repaired or replaced free of charge.

Warranty includes the research of causes of the faults, reparation of the defect and a final inspection of the unit, or part(s).

This warranty does not cover the results of misuse, accident, abuse and tampering or alteration done by anyone other than personnel authorized by OPTIKON 2000 S.p.A.

OPTIKON 2000 S.P.A. reserves the right to ascertain, in case of faults, whether or not the equipment and/or its accessories have been altered, tampered with, in any way, or have been damaged by improper use.

OPTIKON 2000 S.P.A. also reserves the right to modify the equipment and/or its accessories whenever operating techniques necessitate modification(s).

No warranty will be recognized if serial number of the equipment and/or accessories attributed by OPTIKON 2000 S.P.A. is missing, tampered and/or not clearly readable.

Warranty does not include expenses for return shipment of equipment and accessories: all expenses for transport, packing etc. are to be borne by the purchaser.

In case of an expressly requested intervention of our technicians, all travel and hotel expenses will be debited to the client.

OPTIKON 2000 S.P.A. cannot be held liable for damages caused by transportation. If this is the case, the customer should apply at once to the carrier that handled the consignment.

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3 WARNINGS

General

- The Keratron® Scout has been developed and optimised to measure human eyes.The use and the evaluation of the Keratron® Scout in conditions that not comply with this manual, or made by using surfaces having a reflectivity or a shape which is far from those typical of human eyes (for example: contact lenses, surfaces having discontinuity in the tangent or concavity in any of its section profiles, or surfaces such to create multiple reflections or disappearance of some mire) cannot insure to have the same degree of accuracy and thus it is strongly discouraged.

- Situations that create mires jamming can happen on human eyes in limited areas. This must be prevented by insuring a good tearing and good image acquisitions (see in particular the chapters dedicated to the eye acquisition and the last page of this manual), and eventually corrected by properly using “Photo Process” Editing functions. Therefore, you can either adjust mires detection parameters or eventually discard artefacts . In any case, the user must individually check that the mires reconstruction has been adequate before accepting the topographic resulting data as valid.

- Use of accessories and cables other than those provided with the unit may result in an increase of the emissions or in decreased immunity of the system. Portable and mobile communications equipment can affect the performance of the unit.

- Carefully follow the instructions when installing and using the unit , in order to prevent harmful interferences with other devices in the vicinity. If the unit causes harmful interferences to other devices (determined by turning the unit off and on), the user is encouraged to try to correct the interference by one or more of the following measures:

  - Reorient or relocate the other devices.
  - Increase the distance between the equipment.
  - Connect the unit into an outlet on a circuit different from that to which the other devices are connected.
  - Consult your local distributor or OPTIKON 2000 technical assistance.

Environmental

Recycle the Ni-Cd batteries or dispose properly

- Do not dispose of Keratron® Scout as unsorted municipal waste. Collect it separately according to the local laws/regulations on disposal of waste electrical and electronic equipment.

Electrical

- **NiCd batteries: Warning!**
  - The batteries inside this module can explode or leak if put on fire
  - Do not open the Battery Module and do not short-circuit its electric contacts.
  - Do not wet or put into water. You could have electrical shocks or hazard.
- **Caution when inserting/ de-inserting the Docking Base-VK cable**

To insert the cable:

- Turn the base off before plugging the cable to VK.
- Check the connector orientation.
- Insert perpendicularly.
- Tight the blocking screws.

To unplug:

- Turn the instrument off before unplugging the cable to the VK.
- Loose the blocking screws.
- Remove without teasing.

- **Plug the power chord only of a PC having an insulation class II of EN60950 (shortly represented with the symbol), i.e.: compliant EN 60601-1 standard and then lock it by screwing the Perspex Plate in its place**

  The Mains socket-outlet of the OR trolley must be used only to energize equipment compliant with EN 60601-1 standard (or class II of EN60950). The risks that are encountered when equipment, whose compliance with EN 60601-1 is unknown, is connected to the trolley are:

  - the EARTH LEAKAGE CURRENT of the equipment could lead to an excessive EARTH LEAKAGE CURRENT of the system, in normal condition;
  - the ENCLOSURE LEAKAGE CURRENT of the equipment could lead to an excessive ENCLOSURE LEAKAGE CURRENT of the system, in single fault conditions (interruption of common protective earth conductor).

Mechanical

- Block the handle before removing the Videokeratoscope from the staff The arm of the OR trolley base is weight-balanced for an average weight of the Scout VK. Prior to remove the VK, you should block the spring mechanism within the arm by the proper handle, or the staff can hurt your face.

- Insert the pin of the *Slit Lamp Adaptor* into the Slit Lamp hole before tightening the hand-wheel. Tightening of the knob with the pin only partly inserted can permanently deform it.

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4 SYMBOLS

Table shown below reports some symbols approved by I.E.C. and their meaning. When there is not enough room, they are frequently used on medical equipment to enable an easy and fast communication of information and warnings. Sometimes two or more symbols may be assembled to obtain a special meaning.

These symbols are used in the Keratron® Scout and Docking Base labels. Before starting to use the units, you should familiarize yourself with them and their definitions shown in the table.

SYMBOLS PUBLISHED BY THE IEC

SYMBOL	DESCRIPTION
	ALTERNATING CURRENT
	DIRECT CURRENT
	PROTECTIVE EARTH (GROUND)
	ATTENTION, CONSULT ACCOMPAINING DOCUMENTS
	OFF (POWER: DISCONNECTION FROM THE MAINS)
	ON (POWER: CONNECTION TO THE MAINS)
	TYPE B PART APPLIED TO THE PATIENT (BODY)
	TYPE BF FLOATING PART APPLIED TO THE PATIENT (BODY-FLOATING)
	CLASS II EQUIPMENT
	DANGEROUS VOLTAGE
	SEPARATE COLLECTION OF WASTE ELECTRICAL/ELECTRONIC EQUIPMENT

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5 GENERAL INFORMATION

5.1 SYSTEM DESCRIPTION

The KERATRON® SCOUT is a **Modular "Computer Assisted VideoKeratographer"** (also said CAVK in the literature) that, just like the KERATRON®, is designed to measure the shape of the cornea and to represent it as symbolic colour map of the corresponding axial or refractive powers, of its local curvatures or of its elevations in several formats (corneal topography).

The KERATRON® SCOUT is made of:

- a **Videokeratoscope (VK)**, for the acquisition of the image of mires reflected on the eye,
- either a table-top **Docking Base** or a **OR Trolley base** for intra-operative use, to power supply the VK and to communicate via Universal Serial Bus (**USB**) of any PC (not included) to the VK itself
- a selection of **Adapters** i.e. a **Slit Lamp Adapter and Cable**, a **Battery Module**, and an **Head Rest.**

These modules, with some additional accessories like a **Scout "far" Mires Cone** and **Sterile Sleeves**, can create a system to allow to get a corneal topography in one or more of the following operating conditions:

- On a generic Slit Lamp, with the Slit Lamp Adapter inserted into the hole for accessories of the slit lamp itself and a supplied cable inserted between the VK and the Docking base
- Portable, with a specific battery module inserted under the VK and in the docking base, and a head-rest inserted onto the VK.
- Intra-operative, inserting the VK into a staff of the OR Troll base, with a weight balanced arm, which both supports and power supply it

The VK carries 28 mires, which are shaped as back-lighted concentric rings, alternatively 14 black and 14 whites, arranged into the internal conical surface of a cone, made of transparent perspex, called **Mires Cone** which is removable and which carries a opto-electronic couple, made of an IRED and a photo-transistor, set at two opposite sides of its external edge.

The Cone is back illuminated by the *Lamp Board* which contains a tight array of LEDS. Behind the Lamp Board there are the fixation led, focused at a large distance, and the TV Camera.

The photoelectric couple at the edge of the optical head intercepts the eye vertex when this is at the preset distance from the optical head. An electronic circuit (EPCS) eliminates the background light and measures the “degree of coverage”, which is used to accept the acquisition only within a preset range. An array of 5 LEDS at the right hand side of the TV monitor of the VK, indicates the operator how to move forth and back towards the eye. If the eye is not at the right distance the image capture will be inhibited.

The operator thus can only take images, by pressing a footswitch or the OK pushbutton, only when the patient eye is at a preset distance, which is the same distance at which the instrument was formerly calibrated on a sphere having a known curvature radius.

During a test, 2 or 3 photos are usually taken on each eye, then they are processed by algorithms to reconstruct the shape of the cornea at more than 7000 points arranged at the crossways between the 28 black-to-white and white-to-black mire borders and 256 radials or “meridians”.

Graphic routines then interpolates and traces this values in the form of color maps.

The center of the rings is the **corneal vertex**, that is the point of the cornea which is closer to the observing TV-camera, and that is an important reference point for all corneal maps. The **entrance pupil** is also detected.

5.2 TECHNICAL SPECIFICATIONS

PARAMETER	SPECIFICATION
Manufacturer:.....	OPTIKON 2000 S.p.a.
	via del Casale di Settebagni, 13
	00138 Rome - Italy
Model:.....	Keratron® Scout
Regulatory compliance:	93/42/EEC Medical Devices Directive (MDD)
Technical standards:	EN 60601-1 ; EN 60601-1-1 ; EN 60601-1-2

PARAMETER	SPECIFICATION

ENVIRONMENTAL SPECS

Storage:	temp range -10°C to +60°C,
	humidity 0-100% (cond.included)
	atm. pressure 500 to 1060 hPa
Operation:	temp range 0°C to +40°C,
	humidity 0-90% (non condensing)
	atm. pressure 700 to 1060 hPa

ELECTRICAL SPECS

DOCKING BASE AND OR TROLLEY

Input voltage:	100/120/220/230-240 V A.C. select.
Frequency:	50/60 Hz
Power consumption:	60 VA
Line fuses:	220/240 Volt: 1 A T
	100/120 Volt: 2 A T

KERATRON® SCOUT

Input voltage:	14-18 Vdc supplied by the Docking Base, by the Battery or by the OR Trolley
Power consumption:	28 VA

ACCURACY

Simulated K-Readings:	Within +/- 0.25D on a normal cornea.
Focusing	BFS deviation: with Slit Lamp Adapter typical within+/0.15D
	Within +/- 0.25D handheld.To be checked by the “repeatability check” function.
Misalignement.....	Mean deviation on the map: +/- 0.1 with misalignement up to 1mm.

EQUIPMENT CLASSIFICATION ACCORDING TO IEC 60601-1

Type of protection against electric shock :

Docking Base.....	Class I
OR Trolley.....	Class I
Keratron® Scout	Class II

Degree of protection against electric shock:

Docking Base..... Type B

OR Trolley..... Type B

Keratron® Scout ..... Type BF

Degree of protection against harmful ingress of water:

Docking Base..... Ordinary

OR Trolley..... IPX1

Keratron® Scout ..... Ordinary

OR Footswitch IPX8

NOTE
The switches located inside the footswitch are immersion-proof (protection class:IPX8), therefore this accessory is suitable for use in operating room environment

Degree of safety of application in the presence of a flammable

anaesthetic mixture:..... not protected

Mode of operation..... Continuos operation

DIMENSIONS

DOCKING BASE

Height: ..... 80 mm

Width:..... 250 mm

Depth: ..... 150 mm

Weight:..... about 2200 g

KERATRON® SCOUT

Height: ..... 240 mm

Width:..... 280 mm

Depth: ..... 100 mm

Weight:..... about 1000 g

BATTERY MODULE

Height: ..... 95 mm

Width:..... 260 mm

Depth: ..... 120 mm
Weight:..... about 500 g

OR TROLLEY BASE

Height: ..... 1400 mm
Width:..... 600 mm (900 with max arm extension)
Depth: ..... 600 mm (900 with max arm extension)
Weight:..... about 35 Kg

NOTE:
1) Weight and dimensions shown are approximate.
2) Specifications are subject to change without notice

5.3 EMC TABLES

5.3.1 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Keratron® Scout is intended for use in the electromagnetic environment specified below. The customer or the user of the Keratron® Scout should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Keratron® Scout uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Keratron® Scout is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

5.3.2 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Keratron® Scout is intended for use in the electromagnetic environment specified below. The customer or the user of the Keratron® Scout should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	• ±6 kV contact • ±8 kV air	• ±6 kV contact • ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical/fast transient/burst IEC 61000-4-4	• ±2 kV for power supply lines • ±1 kV for input/output lines	• ±2 kV for power supply lines • ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	• ±1 kV differential mode • ± 2kV common mode	• ±1 kV differential mode • ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% U_T (30% dip in U_T) for 25 cycles • <5% U_T (>95% dip in U_T) for 5 sec	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% U_T (30% dip in U_T) for 25 cycles • <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Keratron® Scout requires continued operation during power mains interruptions, it is recommended that the Keratron® Scout be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable. The equipment does not contain any magnetically sensitive components.?	Power frequency magnetic field should be at level characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3V/m 80 MHz to 2.5 GHz	3 Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Keratron® Scout, including cables, than the recommended separation distance calculated from he equation applicable to the frequency of the transmitter. Recommended separation distance: d= 1.2 √P d= 1.2 √P 80MHz to 800 MHz d= 2.3 √P 800MHz to 2.5 GHz where P is the maximum output power rating to the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE:
U_T is the a.c. mains voltage prior to application of the test level
Note 1:At 80 MHz and 800 MHz, the higher frequency range applies.
Note2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Keratron® Scout is used exceeds the applicable RF compliance level above, the Keratron® Scout should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Keratron® Scout unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

5.3.3 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND KERATRON® SCOUT

Keratron® Scout is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Keratron® Scout can help preventing electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Keratron® Scout as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d= 1.2 \sqrt{P}$	80 MHz to 800 MHz $d= 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d= 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rates at maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE:
Note 1-At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2-These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

5.4 CIRCUIT DIAGRAMS

Optikon 2000 S.p.A. will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are repairable.

5.5 COMPOSITION

MODULE	CODE	DESCRIPTION
VIDEOKERATOSCOPE	161204	VK WITH MEMORY EXPANSION AND PUPILLOMETRY unit complete with 28 mires cone, including the pupillometry lamp board, calibration sphere, “Keratron Scout” software (release 3.6 or later), user manual, and an internal memory expansion board to store up to 8 photos.
	162202 (ex ATXE1014)	DOCKING BASE WITH CHARGER Unit. Desktop support base with power cord, USB cable, including a module board to charge battery modules.
	163201 (ex ATXM1079)	OR TROLLEY BASE unit. wheelbase for intra-operative use, complete with power supply cable and OR footswitch, for operating room.
ADAPTER MODULES / KITS	162206 (ex ATXM1076)	SLIT LAMP ADAPTOR KIT: Adaptor slide for slit lamp, complete with “slit lamp cable” to connect the VK with the docking base and footswitch.
	162205 (ex ATXM4017)	BATTERY MODULE 1200 mAh Battery to be inserted below the VK. It can be plugged into the Docking Base battery socket, alone or with the VK, to re-charge and exchange picture data with the PC, at the same time. Working duration after each charge; about 30 min. To be used with 162208 (ex ATXM4078)

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162208 (ex ATXM4078)	HEAD REST (To be screwed onto the VK). To be used with 162205.

5.6 ACCESSORIES

CODE	DESCRIPTION
162210	USB/EPP INTERFACE, including one USB cable and Keratron Scout software CD ROM including USB drivers.
162211 (ex ATXM4079)	SCOUT “FAR” MIRES CONE, including its own calibration sphere.
162212	SPACER FOR SCOUT SL ADAPTOR, to fit the SL adaptor (162206) wit SL having too close distance between hole and projector arm.
162216	KIT FOR ANALYSING CONTACT LENSES,which allows the operator to measure the front and back surfaces of contact lenses. T. The KIT can be used with Scout software version 3.9.0 or later.
169201 (ex GTXG4023)	SCOUT CARRYING CASE. For one Keratron® Scout and accessories
163202 (ex ATXM4094)	SCOUT TRANSLATION BASE WITH HEADREST. XYZ tabletop with joystick, alternative to the SL

196201	SCOUT DISPOSABLE SLEEVE, sterile sleeve for intra-operatory Scout use, with standard cone.
196203	SCOUT DISPOSABLE SLEEVE FOR FAR CONE, sterile sleeve for intra-operatory Scout use, with “far” mires cone.

5.7 UPGRADE KITS

CODE	DESCRIPTION
162203 (ex ATXE1015)	Battery Charger Kit. It upgrades the discontinued Docking Base 162201 (ex ATXE1013) into 162202 (ex ATXE1014) (Service Level).
162204 (ex ATXE1016)	Memory Expansion Kit. It upgrades a VK UTXE1013 into UTXE1014 (Service Level).
162215	Keratron® Scout Pupillometry Upgrade Kit. “Pupillometry Lamp Board” with 140 high efficiency LED (80 of them are SMD amber leds, while others are Infrared LEDs). The instrument provides, beside standard topographies, acquisition of infrared images. Infrared permits accurate pupil tracking in both photopic and mesopic/scotopic conditions. Pupillometry function is supported starting from “Scout” software release 3.6.0 or later, and requires the Scout videokeratographer firmware to be updated to version 3.0. (Service Level)

IMPORTANT NOTICE:

Units produced before year 2000 or during the early months of it, to be updated with pupillometry function, need for the substitution of the “double deck board” (Main Board with code 380260 and CPU Board with code 380280) with the Scout Board (380290).To know the production year call the local distributor or Optikon 2000 S.p.A.

5.8 NOT SUPPLIED ACCESSORIES

COMPUTER minimal requirements:	Pentium III (450MHz) or superior
	RAM 64 Mbytes (absolute minimum, expandable)
	10 GBytes Hard Disk (minimum)
	1.44 Mbytes Floppy drive 3 ½ inches.
	CD Rom driver
	SVGA video board with video mode at least 1024x768 pixels, true-color (16-32 bit).
	USB Port 1.1 or 2.0
	Windows ’95 o ‘98/Me.
	Windows 2000/XP 32 bit only with USB interface Windows Vista 32 bit (only from “Scout” software release 4.3 or later.)
	Color Graphic printer
SLIT LAMP	Any, generic, having an 8 mm hole diameter (between 7.8 and 8.2 mm) within the base shaft, intended for a tonometer adapter.

5.9 DISCONTINUED CODES

MODULE	CODE	DESCRIPTION
VIDEOKERATOSCOPE	161201 (ex UTXE1013)	VK (Videokeratoscope) PLAIN unit complete with 28 mires cone, calibration sphere, "Keratron Scout" software and user manual
	161202 (ex UTXE1014)	VK WITH MEMORY EXPANSION unit complete with 28 mires cone, calibration sphere, "Keratron Scout " software and user manual, including an internal memory expansion board to store up to 8 photos.
	161203	VK WITH PUPILLOMETRY unit complete with 28 mires cone including the pupillometry lamp board, calibration sphere, “Scout” software (release 3.6 or later) and user manual.
DOCKING BASE:	162201 (ex ATXE1013)	DOCKING BASE PLAIN Unit. Desktop support base, with power cord and USB cable.

6 INSTALLATION

6.1 INTRODUCTION

This section details a recommended installation procedure for the Keratron® Scout corneal topography system.

Follow the installation and operating instructions carefully in a step by step manner and, within a short time, you will have gained all the knowledge needed for successful operation of your Keratron® Scout corneal topography system.

6.2 UNPACKING AND INSPECTION

This unit has been packaged to minimize the risk of damage in shipment. Unwrap the package and examine the components. Handle all components with care during unpacking. Use caution cutting the wrapping to ensure that the cut does not penetrate the packing and damage the components. If external or internal shipping damage is discovered, notify the carrier (mail, railways or forwarding agents) and Optikon 2000 as soon as possible. Check the contents against the packing list and notify Optikon 2000 immediately of any discrepancies.

6.3 INSTALLATION PROCEDURE

6.3.1 CONFIGURATION ON THE SLIT LAMP

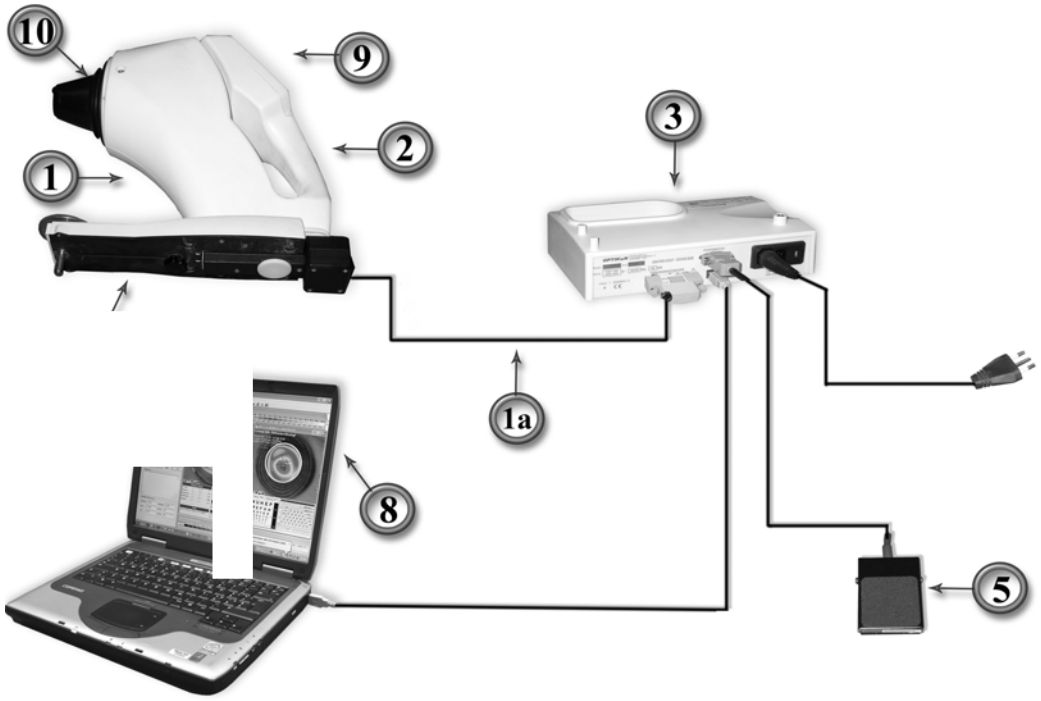


Fig.1 – Diagram of the Slit Lamp configuration

To set up this configuration:

1. Insert the expandable pin of the Slit Lamp Adapter (4) completely in the hole for accessories of your Slit Lamp and then turn its wheel in the direction indicated with “TIGHT”, i.e.: in the clockwise direction. This operation will make the pin to expand so to have a stable coupling. **Caution: avoid expanding the pin when it is not completely the hole, in order not to stress its expander.**
2. Insert one of the two ends of the Slit Lamp Cable (1a) under the VK (1) care to **plug it in the direction that the two dots do match**, and to insert it perpendicularly until the latch clicks.
3. Insert the VK in the slit lamp adapter (take care that it is properly inserted in its slot (not just leaned nor sideway) until the two sphere pins will eventually click.
4. While the Docking Base is turned off, insert the other end of the Slit Lamp Cable having care to **plug it in the direction that the two dots do match**, and to insert it perpendicularly until the latch will click.

5. Connect the footswitch (5) to the Docking Base
6. Connect the PC (8) to the Docking Base via a parallel cable D-sub 25 Male/Female (the male in the PC printer port and the female in the connector “Computer” of the base) and turn the Docking Base on.
   Caution: use only PC having an insulation class II of EN 60950 (shortly represented with the symbol ⧈), i.e.: compliant EN 60601-1 standard, otherwise plug your PC to a mains outlet which is separated by the mains outlet where the Docking Base is plugged.

Fig. 2 – Slit Lamp Cable and Slide connection

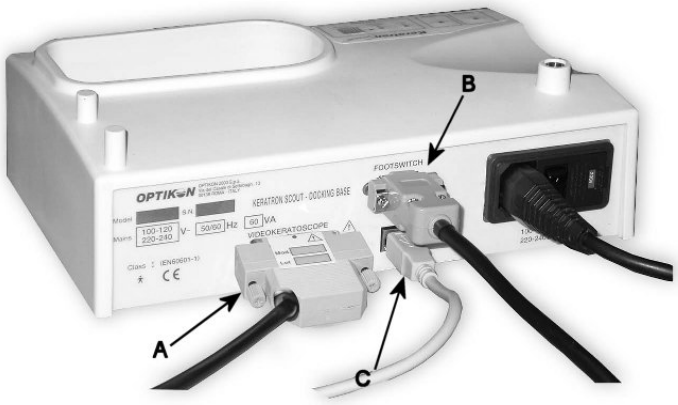


Fig.3 : Slit Lamp configuration: Docking Base cables connection

6.3.2 "PORTABLE" (BATTERY OPERATED) CONFIGURATION

For this configuration, referring to fig.4:

1. Insert the Battery Module (11) under the VK and screw the white knob until the two parts do match tightly.
2. Insert the Headrest (12) on the top of the VK.
3. For a correct acquisition, follow the instructions in the paragraph "How to… Acquire a good image in Portable configuration"

With the Battery Module, in particular:

1. Turn the VK on, by pressing the OK pushbutton for about 1 second. At this point, you can acquire up to two images (8, with the memory expansion). The numbered LED at the left side of the display panel show how many pictures you have taken.
2. In order to download the images to the PC, insert the VK along with its battery module into the Docking Base and then start "Acquire" "New Image" at the PC. If you turn the base off while the VK is inserted, this will turn it off too.
3. To reload the battery, you can leave the complete instrument, or the battery module alone, at all time inserted in the base switched ON. The normal complete charge time is about 15 hours, and that way the battery can stay in its place at all times. If a fast charge was necessary, just push the "fast charge" button. Removing shortly the battery, or switching off the base (or a battery warm-up), will turn back the base to the normal charge.

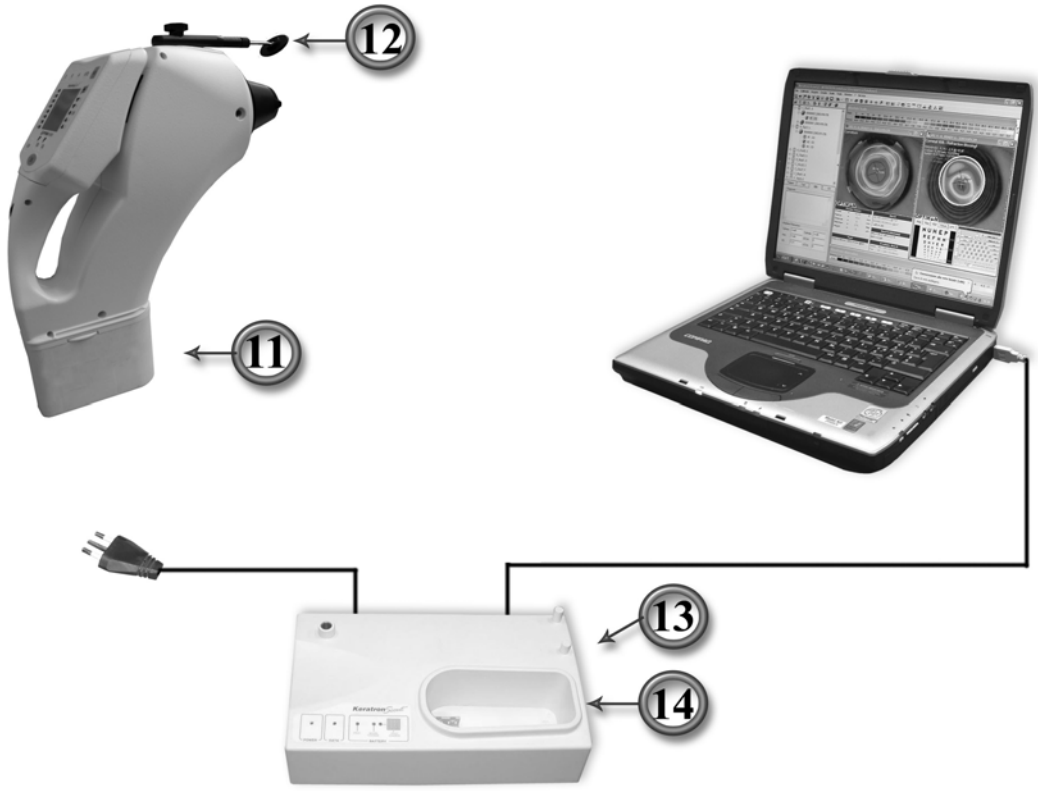


Fig.4 – Handheld Configuration

It's strongly suggested, after every move, to make a calibration, before the test.

NOTES:
When the battery is almost out of charge, a red led will turn on the display panel, and a random be-beep will warn you that you still have a few minutes in order to download and save all the images, and to put it back to charge, too. You should then remember to recharge the battery as soon as possible (within days).

The red battery LED could turn of in case the battery had warmed up too much. In either case, you should leave the instrument to rest in the Docking Base for a while.

When the VK with the Battery Module is not in use for about 90 seconds then, in order to spare the batteries, a timeout circuit will turn off the cone lights and the display. The OD and OS LED will keep blinking. To wake up back the VK after timeout, just press any key (i.e.: the OK button).

6.3.3 INTRA-OPERATORY CONFIGURATION

For this configuration (refer to Fig.5):

1. **Caution: always block the wheels under the basement of the *OR Trolley Base* (18).**
2. Turn the OR base switch OFF. Connect the PC to the *OR trolley base* through a USB cable, connect the *OR Footswitch* to the base and turn the OR base ON.
3. Insert the VK into the staff (22) and connect the connector to it. **Caution: before inserting the connector in the VK take care that the OR Trolley Base is OFF.** Tight both the side knobs (then the *Mires Group* (23) can be tilted by the knobs themselves). Then release the arm (17) by loosing the knob located on the arm itself.
4. **Caution: for a sterile use, it is appropriate to envelope the entire VK by a disposable *Sterile Sleeve*. For the proper insertion and usage of the sleeves, refer to the relevant instruction for use.**
5. At this point, the images can be acquired by setting the VK parallel to the patient and using the keys upside-down on display (21) (with the help of an assistant, if it is not covered with the *Sterile Sleeve*). To take the image you can use the footswitch or the OK button at the bottom left, by keeping it pressed and getting close to the eye until the acquisition is automatically taken. The last image can be canceled by the CLR button, or it can be processed by the P key and the test saved by the S key. As an alternative the acquisition can be activated from the PC keyboard, by pressing “ctrl”+”D” or “ctrl”+”S”. You can also toggle “Auto-Trigger” by “ctrl”+”Spacebar” (Caution to avoid harsh movements and to clear bad shots). To enable P-S-C keys, and for more explanation about “auto-trigger” function, refer however to Options “Process” and to the ”Help-on line” directly on your PC.

WARNING

Caution: use only PC having an insulation class II of EN 60950 (shortly represented with the symbol ⧈), i.e.: compliant EN 60601-1 standard.

Otherwise plug your PC to a mains outlet independent from the OR Trolley. In such a case the PC (as well as the printer, if it is connected during the operation) must also be kept at a minimum distance of at least 1mt from the patient just like any non-medical equipment.

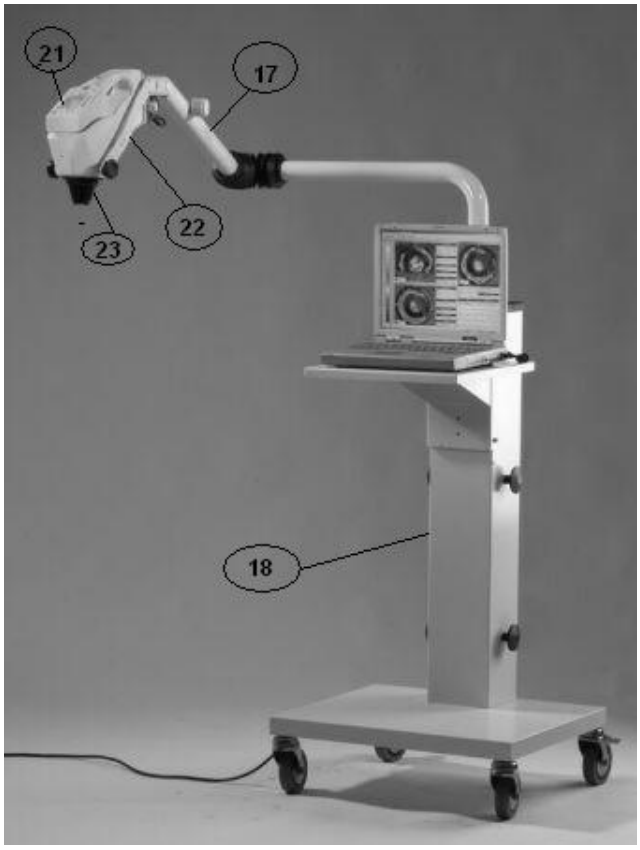


Fig.5 - Intra-Operatory Configuration

6.4 SOFTWARE INSTALLATION

6.4.1 INTRODUCTION

The Keratron Scout software does not require special instructions because it is driven by an appropriate Setup program is usually installed when you receive the system.

The following precautions are recommended:

1. The PC must be an IBM compatible, with an operating system Windows 98/Me or Windows 2000/XP only with USB interface.
2. The screen properties can be set in any mode, but it must be a “true color” (65K or 16M colors). It is however recommended a screen size of at least 1024x768 pixels.
3. Do not alter any of the system files installed by the Keratron Scout Setup software, nor any file in the Database unless you have a specific competence on the PC and LAN management. If such is the case, refer to the Service Manual.

The update of the software of your Keratron® Scout is easy and does not alter your database, or your instrument calibration, or your preferred settings that are stored in the hard disk.

You must first uninstall the previous version, and then install the updated version of “Keratron Scout Setup”. The most recent version can be also downloaded after registration from the web Internet site of Optikon 2000: http://www.optikon.com/.

> NOTE :
> In Windows 2000 and XP operating systems, you must have system administration (Administrator) privileges to install the software.

> NOTE:
> A printer has to be installed and set as default before running the Scout.exe software

6.4.2 DOWNLOAD THE KERATRON SCOUT FROM THE WEB

Go to the Web site http://www.optikon.com/scoutmain.htm

The procedure is different depending on if you are registered or not.

IF YOU ARE NOT REGISTERED

- Click the hyperlink “Go to the registration page”
- Fill all the items, and click the “Register Me” button.
- You will be enabled to download within 24 hours, receiving a confirmation e-mail from Optikon 2000.

IF YOU ARE ALREADY REGISTERED

- Click the hyperlink “Go to the download page”
- When prompted, write your Username and Password, then click OK button.
- Create an empty folder on your Hard-Disk (e.g. “C:\ScoutSW”)
- Right-click on the hyperlink Setup.exe, choose “Save Target As” when prompted and save it in the folder you have created.

6.4.3 KERATRON SCOUT SOFTWARE INSTALLATION

Both if you are installing the Keratron Scout software from the Web and if you are installing from CD, remove any previous Scout versions from your PC before install the new Scout software.

If you are installing the software from the CD-ROM :

- Insert the CD-ROM into the reader.
- Wait a few seconds, an HTML page will be loaded.
- Choose the “English” hyperlink.
- Choose the “Install Scout Rel xx.xx, for Keratron Scout & Keratron Bridge“ hyperlink.
- Choose “Run” when prompted.

If you are going to install the downloaded version:

- Using “Windows Explorer” select the folder where the downloaded files are.
- Run the “Setup.exe” by double-clicking on it.

Indipendently if the installation has been made from CD or downloaded version, the setup procedure could notify some messages, like DLLs version conflicts etc.
See the troubleshooting section in this manual (see 9.1.1) for the proper action.

6.4.4 IMPORTING OLD KERATRON® TESTS

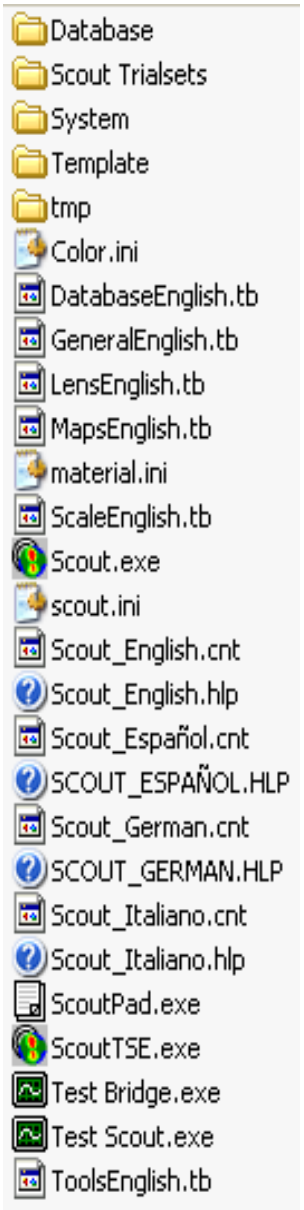
The exams file format of Keratron® Scout is different from the old Keratron one®. Old exams to be used in Scout software have to been “translated”. This operation can be done with the import function:

- From menu bar choose “File” -> “Import tests…”.
- Select the folder that contains the tests and click the OK button.
- The “Test Manager” window will appears.
- Click on the “Import” icon.

Before importing it’s advisable to have these remarks:

- If there are many tests do not import them all together, try to import a little group, and check them.
- Make attention to the list showed il the “Test Manager”, verify that each name, surname, sex, DOB, test number and test date are imported correctly.
- You can change the import parameters using “Tools” -> “Options…”, select the “Database” section and click on the “Conversion Options…” button.

6.4.5 KERATRON SCOUT SOFTWARE ANATOMY



Default database folder.

Scout Trialsets folder (void after first installation).

Keratron Scout system files. Be careful to this folder!!

Put here imported print-templates, and those you create new.

The SW puts here temporary files.

*.tb	Toolbar settings
Scout.ini	Software settings
*.cnt	Help contents files
*.hlp	Localized help files
ScoutTSE.exe	Trial-set editor for Keratron Scout lenses.
Scout.exe	Main program
ScoutPad.exe	Print template generator
Test Scout.exe	Test tool Scout communication
Test Bridge.exe	Test tool Keratron communication
Color.ini	List of available lens colors
Material.ini	List of available lens material

6.4.6 SCOUT CUSTOMIZATION

You can customize/change SW behaviour and toolbar buttons.

Change the SW behaviour using the “Options” window under the “Tools” menu.

Customize the toolbars simply right-click on it.

6.4.7 USB DRIVERS INSTALLATION

With the computer at the Windows desktop, insert the supplied CD-ROM that contains the drivers.

First, connect the cable to the PC USB Port , and then to the USB port of the Docking Base.

Switch the Docking Base on and follow the instructions below according to your Operating System.

Windows 9x/ME

As the interface is a Plug & Play device the operating system will recognize it and will display the Dialog Box “Add New Hardware Wizard”.

Now:

Click on the **Next** button

A new windows will appear and select the radio button “**Search for the best driver for your device (Recommended)**”

then go on clicking the **Next** button.

In the next window select only “**Specify a location**”. Then clicking on the “Browse” button select the directory **software\drivers\EPPUSB_Bridge\Win9x** in the CD ROM as shown in the figure 1.

Installazione guidata Nuovo hardware
Sarà effettuata una ricerca dei nuovi driver nel database dei driver sul disco rigido e in tutti i percorsi seguenti selezionati. Scegliere Avanti per iniziare la ricerca.
Unità floppy
Unità CD-ROM
Microsoft Windows Update
Specificare un percorso:
d:\software\ drivers\EPPUSB_Bridge\Win9x
Sfoglia...
< Indietro
Avanti >
Annulla

Figure 1

Click the **Next** button.

The computer will display a message confirming that the suitable driver has been found and is going to install it.

Continue with the **Next** button.

“Add New Hardware Wizard” will end the installation with Figure 2

Figure 2

Click on the **Finish** button.

Windows 2000/XP

> NOTE :
> You must have system administration (Administrator) privileges to install the USB drivers.

As the interface is a Plug & Play device the operating system will recognize it and will display the Dialog Box “Found New Hardware Wizard”

Click on the **Next** button.

Select, in the next window, the radio button “**Search for a suitable driver for my device (Recommended)**” and then click the **Next** button.

Among the options of the next window select only **“Specify a location”** and click the **Next** button.

Then, the operating system will ask for the location of the files to copy.

You have to specify the **software\drivers\eppusb_bridge\Win2k** directory for Windows in the box below “Copy manufacturer’s files from:”.

Click the **OK** button to start the installation.

The installation will be started by the click of the **Next** button in the window that confirms that a suitable file was found and it is ready for installation.

Found New Hardware Wizard
Completing the Found New Hardware Wizard
Optikon 2000 Keratron Bridge Interface
Windows has finished ins:alling the software lor this device.
I o clcse this wizard, click Finish.
< Back
Finish
Cancel

Figure 3

The window displayed in the Fig.3 confirms that the driver has been properly installed.

Complete the by clicking the **Finish** button.

6.4.8 CONFIGURING KERATRON SCOUT SOFTWARE

The next phase consists of enabling the USB communication in the Keratron Scout software.

Start the Keratron Scout software. In the menu bar select Tools then select the item Option....

The dialog box shown in fig.4 will display.

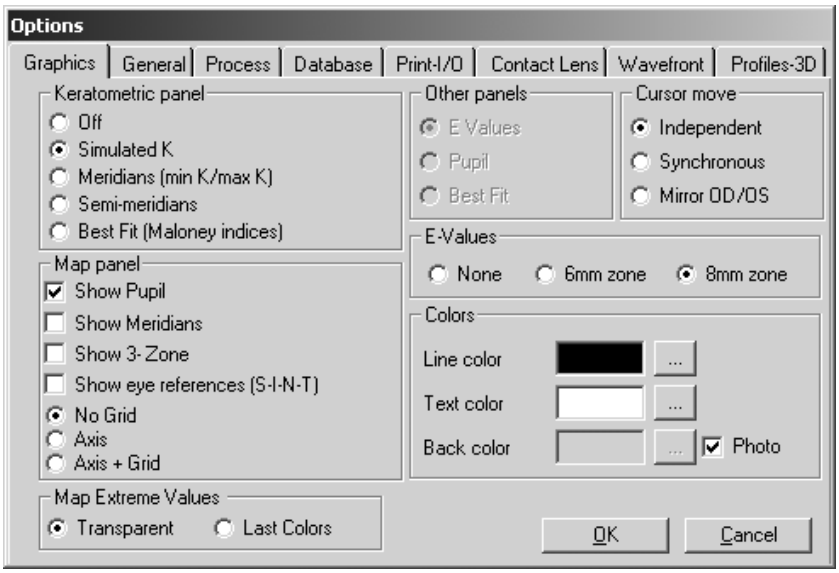


Figure 4

Select the tab labeled “Print” and the dialog box will display as shown in fig.5.

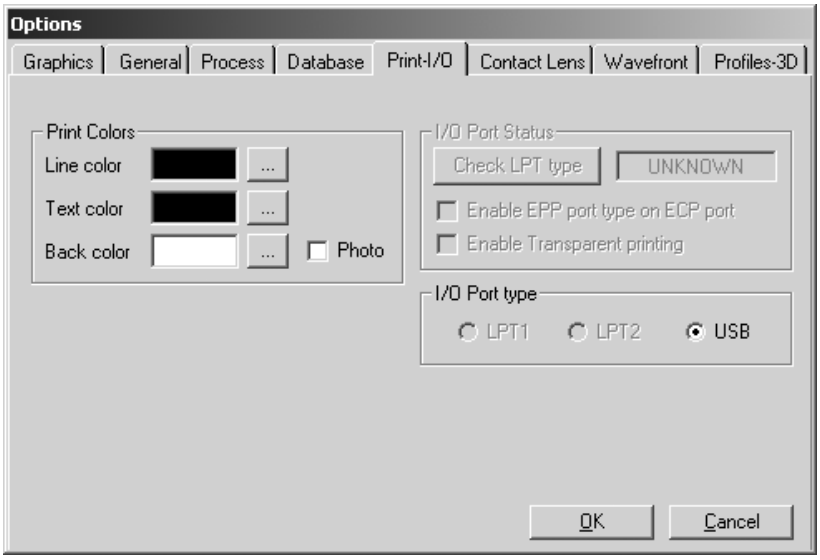


Figure 5

Select in the Port Type frame the **USB** option then press **OK**.

6.4.9 UNINSTALL KERATRON SCOUT SOFTWARE

We can imagine two different methods: the first one uses the Windows standard uninstall procedure :

1. Start “Control Panel”.
2. Click on “Add/Remove Programs” icon.
3. Select the “Keratron Scout“ item.
4. Click on the “Add/Remove” button.
5. Follow the instructions, if the uninstall procedure asks you to remove some DLLs, click on the “Yes to all” button.

The second one calls directly a specific unistall utility:

1. From Windows menu “Start” -> “Programs” -> “Keratron Scout”, choose “Uninstall Keratron Scout” item.

For both methods verify that these files has been really unloaded/deleted from the PC.

- C:\Keratron\Scout.exe
- C:\Keratron\ScoutTSE.exe

- C:\Keratron\ScoutPad.exe
- C:\Keratron\Test Bridge.exe
- C:\Keratron\Test Scout.exe

Finally, restart your PC.

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7 SCREEN AND COMMANDS DESCRIPTION

7.1 INTRODUCTION

In this section only the basic operation are described. For a more comprehensive and updated description of the software functions, refer also to the HELP menu (command or key “?” on the menu bar).

7.2 CALIBRATION

To ensure accurate measures, you are suggested to do the Keratron® Scout calibration often. In particular:

- After any transportation or installation.
- After any Mires Cone removal and change.
- On a periodical base (e.g.: daily or after each turn on) depending on use.

To run the calibration:

- Check, that the sphere radius saved into the PC matches the one reported on the back of the calibration sphere itself. If no, then set it into the CALIBRATE menu (just the first time after installation).
- Start the calibration from the menu or the CALIBRATE button on the PC screen (if the VK is connected to the base through a cable and it is NOT battery operated)
- Press either OD or OS on the VK to start the acquisition
- Hold the body of the calibration sphere between the thumb and the third finger, and fit it well and steady onto the mires cone.
- Turn the back knob by the second finger, until the sphere vertex turns the OK LED on. Turn slightly back and forth so to be sure to be in the middle of the OK zone.
- Press the OK button and wait that the image is transferred to the PC and accepted automatically. If the software cannot find the center automatically, then follow the instructions on the screen.

If the instrument is battery operated (“portable” configuration), after the acquisition, it shall be inserted firmly in the Docking base, and then run CALIBRATE on the PC.

7.3 HOW TO ACQUIRE A GOOD IMAGE

Acquiring an image is the most critical operation of topography. Care must be taken to capture the image moving slowly to the proper vertex distance every time and to avoid bad tearing and *eyelashes artifacts* (see the last page in this manual).

An automatic focusing device located on the cone apex lets you capture images only if the eye vertex is at a correct working distance, provided the eyelashes do no interfere.

From the ACQUIRE menu, select “New Image”; the IMAGE ACQUISITION window will appear on the display.

Press either the OD or the OS key to select the eye to be examined; an intermittent sound will indicate that the instrument is ready to begin acquisition (pressing the CLR key will cancel the selection and allow a new one).

7.3.1 THE SLIT LAMP CONFIGURATION

> When moving forward the Keratron® Scout, be careful not to hit the patient with the cone.

Adjust the cone vertically and slightly rotate the adapter sideways so to avoid that the cone hurt the nose or the eyebrow of the patient. Adjust the height of the table and of the chin rest as to obtain the most stable position.

Use the joystick of the slit lamp to center the cross on the monitor at the center of the rings while getting near to the eye. It is not necessary to be extremely scrupulous in this operation, as the software will compensate automatically the possible decentration. If the acquisition time should be too long, the patient eye could get tired and the lachrymal film could break.

While centering, use the joystick of the slit lamp to get to the proper distance from the eye. The lower LED, with an arrow pointing upward indicates that you should move closer to the eye. The upper LEDS with arrows pointing downwards indicate that you should move back from the eye; if the arrow inverts its direction pointing upwards, the correct focusing has been exceeded. Correct focusing is reached when the central OK LED is on.

You may capture up to eight images.

Discard the bad pictures at once, if they were clearly moved or taken while the patient was blinking, by pressing CLR.

It is advisable that, as your first training experience, you take 6-8 pictures on the same eye and to check their repeatability by “Acquire”, “Repeatability Check” menu, until this is good.

As a standard procedure, you are then suggested to take 3-4 pictures per eye in order to check repeatability, and then to save only the best one (or two)

> Caution:
> To move the Scout do not use its handle, but the slit lamp joystick. Use the footswitch to acquire, and avoid using the OK key.

During the acquisition of an image, the Keratron® Scout emits a series of “beeps” changing in pitch and rhythm. This is meant to be an audio cue for the operator when aligning an eye for image capture. Listen to the beeps to get familiar with the cues. Perfect focus has its own distinct sound. The audio cues enable you to concentrate more on the video image on the CRT rather than on the arrow indicators.

Suggestion: To obtain a quick and reliable acquisition, go just a little closer to the eye than OK, ask the patient to blink then to OPEN BOTH EYES WIDE then, keeping the switch pressed, move back slowly and thus acquire the image automatically. If the patient blinks, discard the photo and repeat.

Once you have captured an image by pressing the footswitch – or the OK key if the PC is in acquisition mode -, the image will be automatically transferred and added to the previous ones. If you press the CLR key, you can delete the image last taken.

7.3.2 THE PORTABLE CONFIGURATION

Acquisition in portable or handheld mode is affected by a larger number of perturbing factors than with LAF (both patient’s and operator’s movements, and possible rotations in 3D) and therefore it requires more experience and practice.

Nevertheless, after a short training, and with the following trick-and-tips, it is possible to learn to take quickly results having a repeatability as good as those that can be obtained with the Slit Lamp configuration.

1. Sit the patient so that his head touches a wall without tilting up, and so to stay just in a higher position than he is (fig. 6).
2. Put the disk extension of the headrest steady on the patient’s forehead, possibly helping with the other hand.

3. Tilt the cone possibly in its horizontal position. Only with patients having a leaned forehead or with children orientate the cone to 5° or 10° upwards (1 or 2 clicks). In such cases, however, you could need to be even higher than the patient. The cone should however approach close to the eyebrow (figures 7), so to avoid that the lower lid covers the eye too much (figures 8).
4. Press OD or OS to start acquisition. Get near to the eye until reaching the OK position.
5. **Take care that the protrusions of the mires cone do not hurt the patient's eye!** To avoid this, it is important that you centre the reflected rings with the cross in the display from the very beginning and that you keep them centred at all time while you advance by pushing on the headrest up to reach the OK position. Avoid pivoting sideways the VK by your holding hand and instead looking for the optimal point where to place the headrest disk, with the help, if necessary, of the other hand.
6. Ask to the patient to blink and then to open wide both eyes. Then get close by slightly overcoming the OK position, press and keep pressed the OK button and then get back very slowly until you get an automatic capture.
7. If the picture is moved, then erase it at once by pressing CLR and then proceed with next acquisition. Capture up to 8 picture (at your first experience) on the same eye and 3-4 per eye, in your daily practice. On the PC, discard only the very moved or bad ones and then run "Process All". Do "Acquire" "Repeatability Check" and repeat until you can get good results. Eventually save only the 1 or 2 best ones.

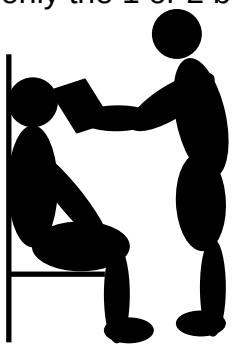
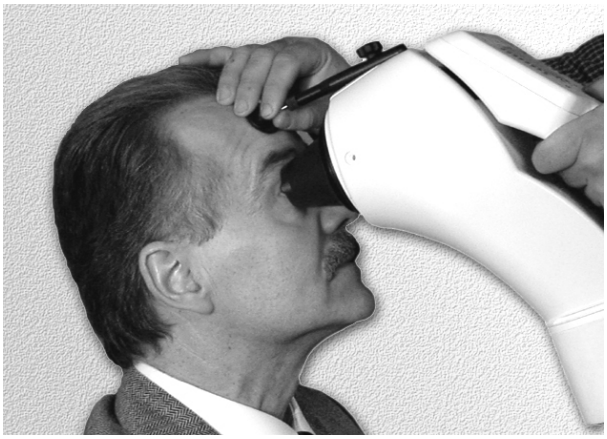


Fig.6 Patient Operator position



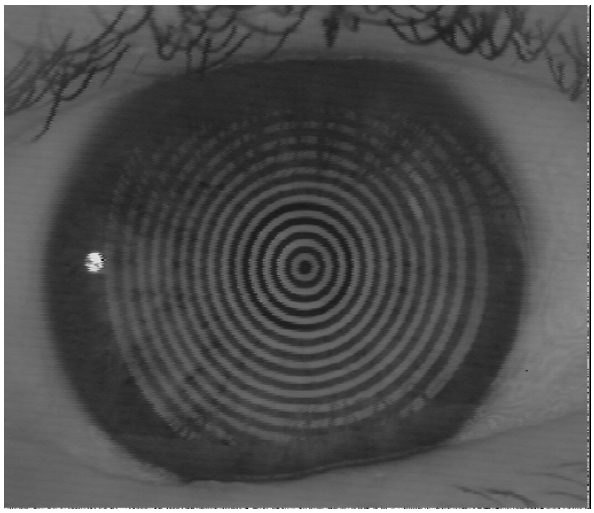


Fig.7 – Correct Approach

Fig.8 – Bad Approach

NOTE:
It is very important that the patient opens BOTH eyes VERY WIDE, to avoid typical *eyelashes artefacts* (see the last page in this manual). If the eyelashes shadows reach the horizontal line passing through the centre in the picture, they can fool the detection system and you will get a map with abnormally high curvatures. In case of doubt take more than one photo and check for repeatability. If necessary help the eye aperture with your fingers and re-instruct the patient to open widely.

NOTE:
Do not waste time to align perfectly the cross within circles. Even a 4-5 rings error generates an error lower than 0.1 D. It is more important that eyes are wide open.

NOTE:
If the tear film is bad, ask the patient to blink. If any dust or grime doesn't go away, ask him to gently rub his eyelids.

7.4 HOW TO PROCESS, PRINT AND SAVE IMAGES

After “Acquisition”, you can process individual images by double clicking on them, but it is advisable to process all of them by the “Process All” menu or icon-button.

Processing an image means analyzing the circular mires’ reflections on the cornea to obtain a topographic map.

The rings centering and tracking is made evident in the Photo-process window. Here you can check how and where within the map this has been made properly, without artifacts, and here you can intervene by adjusting processing conditions and/or erasing bad tracks.

To choose the graphic representation, which will be automatically created and left on the desktop during processing (including the Photo-Process window), choose “Options” from the “Tools” menu; then choose “Processing”.

From “Default Map Type” section choose the required representation, and then press OK.

Apart from that setting if, for instance, starting from an Axial map you want the Curvature to be displayed, click on the above-mentioned map (the title bar is activated) and then, from the menu, choose “Make” “Axial”.

To activate the various types of keratometric data, choose “Options” from the “Tools” menu. As an alternative, you can click on any map with the right button mouse and just select “Options”.

The effect of a change in graphic options is immediately applied on all maps already displayed on the screen, though it can take a few seconds.

Finally, select the “Save Test” menu or icon button.

Discard all images except for the best one for each eye. This will save space on disk and will speed up review.

If you did not do it before, fill in patient form. Always put the name and date of birth, the sex, the group, diagnosis and operator (see Patient Form).

These keywords will be essential to find tests into selected groups, even when your database would become huge.

To print the screen, simply choose from the “File” menu “Print Screen”. You can print while in Acquisition mode only if the “Transparent printing” is enabled.

To print one or more tests, both those saved and stored and those displayed on the screen using print templates, by the “Print” menu or icon-button, or from the “Test Manager”.

7.5 PUPILLOMETRY

In this chapter are described only basic information on how pupillometry images shall be acquired with a Scout videokeratoscope with pupillometry lamp board (161203/161204).

You will find detailed information of: pupillometry functions, how pupillometry is represented on Keratron® Scout maps and considerations about pupillometry, in the ***on-line-Help*** of "Scout software", release 3.6 or later.

IR-Pupillometry picture

To acquire an IR-Pupillometry image, start image acquisition as usual, by pressing OD or OS on the VK display panel, then press once the inverted [P] button above the display (figure 9). You will see a white square at the bottom right of VK display (A) and the cone will darken.

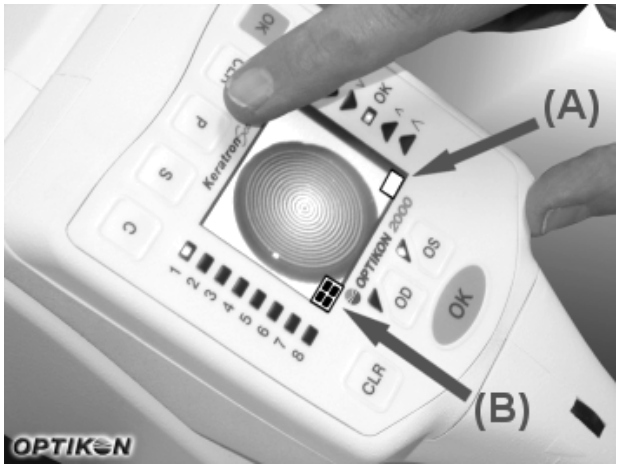


Fig.9 – Toggle among pupillometry modes

Fig.10 – Accommodate both eyes to dark

Then wait for at least 10-15 seconds in order to allow the pupil time to accommodate to its size to dark conditions. Then acquire the dilated-pupil picture as a normal capture. Usually you need to take just one IR picture, whose pupil track will be then associated to all map views. You can however take more than one IR picture for a subsequent choice, or for averaging (see “Help”)

> IMPORTANT NOTICE
> You must keep the room illumination at a very dim level (for scotopic/mesopic conditions) and cover the contra-lateral eye with an eye-occluder (figure 10). Avoid any direct light source (lamps or bright objects), behind your shoulder that would be in the visual field of the patient. Such illumination sources will cause the IR-pupil measurement to be significantly smaller than it actually would be.

Mixed (IR+visible) Pupillometry picture

If you press the [P] button twice then you start a "Mixed" illumination pupillometry image. You will see a white box with a cross at the bottom left of VK display (B in figure 9). The cone will lit up again and acquisition of the picture can be taken as usual (note a 3rd pressure of [P] as well as stopping acquisition by [Clr] and restarting, will return the cone in the “standard” light mode).

Mixed acquisition mode, useful with some very low-contrast pupil, shall be attempted only after other methods to track it failed. See first in the ***on-line-Help*** of Scout software Release. 3.6.0 or later, the chapters about “Pupil Editing” and “Pupillometry”.

8 CLEANING, STERILIZATION AND MAINTAINANCE

The medical personnel must take the responsibility to keep existing instruments and equipment functioning properly. The following simple steps serve as practical guidelines in establishing your care and maintenance program.

8.1 CLEANING AND DISINFECTION

The forehead-rest must be cleaned with alcohol or bactericide disinfectant before use with any patient.

Sometimes, and whenever there is a possibility for skin allergy or cross infection, the external black conical surface of the optical head can also be cleaned with disinfectant, having care not to touch the two small photo-electronic tips of top of the cone.

On special occurrences, or on a monthly basis, the optical head can be removed and cleaned inside. To perform this operation you must:

- Grab the mires cone by its round flap with your full hand and remove it.
- Clean inside the hole by blowing with a cleaning compress air can (or by low-pressure compress air).
- Re-insert the “cone” in its proper position. Press it firmly against the videokeratoscope.
- Run a calibration, as described in the CALIBRATION SCREEN.

8.2 STERILIZATION

The Keratron® Scout videokeratoscope, computer and accessories used, but not those intended for the intra-operatory use, do not require sterilization since they are not expected to come in touch with the patient.

> CAUTION: In intra-operative mode the Videokeratoscope shall be covered with the proper disposable sterile sleeves just before use. Refer to the relevant instructions for use for a proper use of the sleeves.

NOTE:
To maintain system safety, the compliance to EN60601-1 leakage current limits should be tested at least once a year. Please, inquire with the Bioengineering Department in your clinic or with your local Optikon Distributor/Service Center.

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9 TROUBLESHOOTING

9.1 SOFTWARE INSTALLATION

While the installation utiliy is copying Keratron Scout files in the PC hard disk the following message could appear:

THE FILE YOU ARE COPYING IS OLDER THAN THE FILE PRESENT IN THE PC

- In this case the first choice is to leave the newer file (already in the PC), without overwrite it with the older version.

After the installation check the proper working of software running and test Scout program. If any error messages appears (Automation error, DLL xxx.dll not fount etc) the suggested actions are:

- Unload the Scout software (see §6.4.2)
- Reinstall it overwriting the files when prompted.

9.2 THE SCOUT.INI FILE

This files contain all the settings you make using the “Option Panel”, and other settings provided by the SW.

This file must be used if:

1. The SW hangs when starts.

   When this occurs try to rename (**not delete!!**) the “Scout.ini” file and restart the SW.

2. Runtime error exporting tests.

   When this occurs open the Scout.ini file and then, in the “[Export]” section, check the “path” key, probably it is pointing to a network path not available at the moment, or to an external drive not connected. Delete this row “path=x:\nnnn\mmmm\” and retry.

9.3 SHARING KERATRON® SCOUT WITH OTHERS

If more than one user performs tests with Keratron® Scout, how can I separate tests to avoid confusion ?

There are two ways to proceed:

- Create your own “group” (e.g. your name) into the database, and save every test you perform in that “group”. (**not recommended**)

or

- Create more databases. (**recommended**)
- Create one folder fo each user (using “Windows Explorer”).
- Create one database for each folder (using “Keratron Scout” function, “File” -> “New Database”).
- Every user will point to his database using “File->Open Database”, or from “File->Recent Database” list.

9.4 CHANGING THE PC

- Backup the Database(s) (on network, cd-rom…).
- Backup the “C:\Keratron\Scout.ini” file (options, settings, MRU path).
- Backup the “C:\Keratron*.tb” file (toolbar settings).
- Change the PC.
- Reinstall the Keratron Scout software.
- Reinstall the trial-sets.
- Restore the database(s) (from network, cd-rom…).
- Restore the “Scout.ini” into the “C:\Keratron” folder.
- Restore the “C:\Keratron*.tb” file (toolbar settings).

NOTICE
If you have installed some external programs, you have to re-enter the passwords.

9.5 MISCELLANEOUS PROBLEMS

The following guide lists some malfunctions which may occur, the symptoms and the corrective actions. If the Keratron® Scout system remains inoperative even after performing the corrective actions indicated below, contact Optikon 2000 S.p.A. sales/service department.

SYMPTOMS	CORRECTIVE ACTION
A.C. Powered Units	
Keratron® Scout completely inoperative.	a. The Docking Base a.c. power cord not connected. Connect power cord to control console and the power source. (See § 6.3.1) b. A.C. line fuse blown. Replace the line fuse. c. The Slit Lamp Cable has been not properly inserted or Keratron® Scout side or Docking Base side. Insert the cable properly on both sides.
Battery Powered Units	
Keratron® Scout completely inoperative.	a. The Battery Pack is not properly inserted. Test the insertion of Battery Pack. (See § 6.3.2) b. The Battery Pack is exausted. Recharge it.
Acquisition and Processing Images	
The acquired image is broken into horizontal blocks.	a. Check whether the Scout.exe and Tstscout.exe have been run at the same time (look at the Windows ToolBar). b. Check the presence of resident software that could interfere with USB port. Check the icons in Windows Toolbar (bottom right side) and de-activate them.
The map colors are not uniform, they sometimes change or they look dithered (“strange” colors).	Check the “screen” settings, if they were 256. Keratron® Scout requires a “True Color” mode, either 16, 24 or 32 bit.
The VK is not detected when in acquisition mode or when attempting to.	a. Check that the docking-base is ON and that the VK is power supplied (LEDs OD/OS blinking alternatively). b. Check that the USB Cable between Docking Base and PC is inserted. c. Check the cable between the docking-base and the VK.

SYMPTOMS	CORRECTIVE ACTION
	d. In the motherboard BIOS setup utility check whether the USB port has been enabled.
The Scout software cannot find some file (for example, DLL, INI files...).	a. If it is possible, track the missing or damaged file and try to copy, move or overwrite it. b. Un-install the Scout.exe software, launch the PC and install the Scout software again. c. Re-install Windows and then Scout software.
When battery operated the images acquired appear interrupted or not complete.	a. Insert the Scout in the docking base FIRST and THEN launch the acquisition. b. Check the proper insertion of the Scout in the docking-base socket.
When more images are processed the windows are empty or not complete, the maps are black or absent, or the pictures within the “accelerators” (icon buttons) disappear, or other non usual behaviours on windows update.	a. Too few RAM memory in the PC available b. Check from menu ‘?’ ‘About’ ‘System Info...’ the percentage of system resources available. If it is less than 10%, close all possible programs that engage it or increase the RAM memory in the PC (suggested 64 Mb). However limit the excessive simultaneous use of resources in the system.
The texts within the buttons or in the windows labels are non readable (cutted or new paragraph)	a. Check the video board and its drivers (try different video mode and settings). Check that no programs or settings in Windows can be cause of such a behaviour (for example Windows plus settings). b. Check the Windows “video settings” within “Screen properties”.
	Database
The database is locked, it is not possible to open nor to close a database.	a. Update the last software release and retry. <u>Solution A</u> a. Exit the Scout program. b. Rename the folder of the database in use (the selected database is indicated ot the bar at the top of the Scout desktop) e.g.: from “C:\My Documents\Database” in “C:\My Documents\Database_old”. c. Launch Scout program. d. By the “New database” menu command recreate the database “C:\My Documents\Database”, if the database was “C:\Keratron\Database” you don’t need to recreate it because it is the default database and therefore it is automatically created by the program if it was not found.

SYMPTOMS	CORRECTIVE ACTION
	e. Import tests from the folder “C:\My Documents\Database_old”. Solution B (if you are working in a LAN group) a. Exit (all) from the Scout program b. Open the file indtest.mdb (from the folder reported at the top of the Scout desktop). c. Open the ‘tabLock’ table . d. Modify the first record of the table from the present value to ‘Unknown’. e. Save and exit CAUTION! The Scout database is saved with DAO 3.5 (Access ‘97). If you are using an Access version more updated, do not modify (saving) the database with the new version, because the modified file would not be readable from the Scout. If it was due to a wrong manouvre by a non expert user, reload the database and save it again with the DAO 3.5 version (“prior Access database version”)
No test is visible in the “database explorer”	a. An empty database has been selected. b. Check whether the ‘Group’ selection has been pressed and no “Group” is present in the database. c. Check whether the ‘Operator’ selection has been pressed and no “Operator” is present in the database. Note: The selections “Group” and “Operator” are of “toggle” type, and are independent from alphabetical or chronological selection
Default settings do not correspond to the last ones, or the database looks “disappeared”	a. Exit the Scout program b. Cancel o change the name (for more security) to the file “C:\Keratron\Scout.ini”. c. Restart the Scout program and set the preferred options again.

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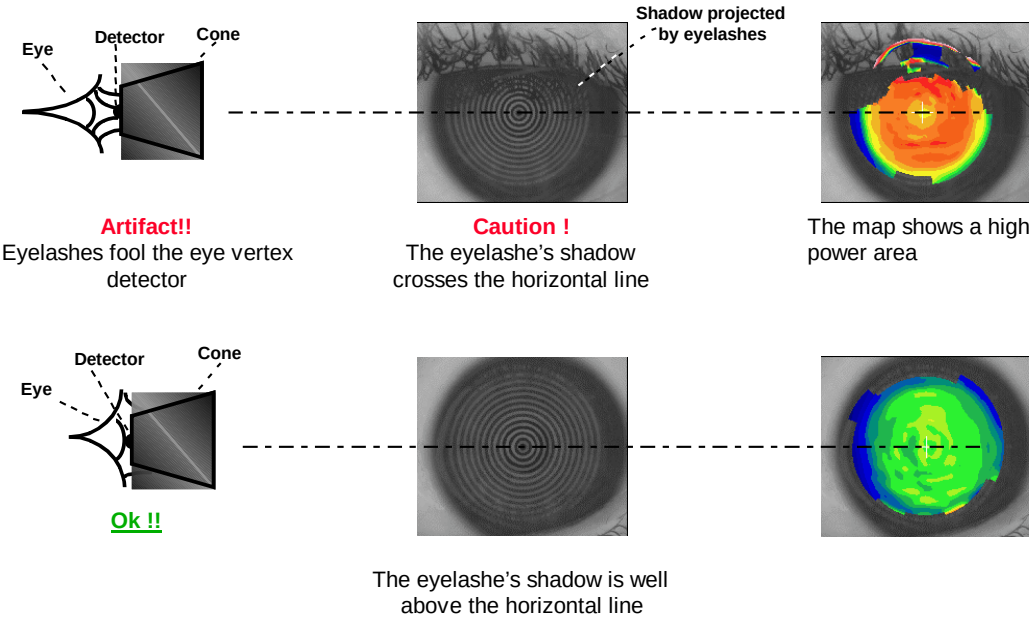
11 APPENDIX

Eyelashes Artifact



Suggestions:

- Instruct the patient to WIDELY open BOTH eyes (if necessary you can help the eye open with your fingers outside the cone).
- Acquire at least 2 images for eye, check for repeatability, eventually saving only the best ones.